INSULIN PUMP CRITERIA

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to deliver a continuous subcutaneous insulin infusion (CSII) into the body. Typical devices have a two to three day supply of insulin connected to an infusion set attached to a small needle or cannula programmed to deliver a steady basal amount of insulin and release a bolus dose at meals and at programmed intervals. The purpose of an insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control and prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. An insulin pump is considered Durable Medical Equipment.1

In many people, CSII or multiple insulin injections can provide equivalent improvements in control. Some clinicians recommend CSII only when 3 or 4 daily injections fail to provide adequate control. CSII may also be appropriate for those strongly motivated patients whose daily schedule makes conventional therapy less effective. Use of CSII requires care by skilled professionals, careful selection of patients, meticulous patient monitoring and thorough patient education and training.

The Utilization Management Committee of Total Health Care will consider authorizing an insulin pump for a strongly motivated diabetic member who has experienced sub-optimal control of his/her serum glucose levels despite consistent compliance with conventional medical management of their diabetes. The qualifying member would be required to be compliant with their medical management program and meet the criteria listed below.

External insulin pumps may be appropriate for the treatment of diabetic patients who:
(1) meet the updated fasting C-Peptide testing requirement or are beta cell autoantibody positive; and (2) satisfy the remaining criteria for insulin pump therapy as described below.

1) The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or must be beta cell autoantibody positive

Updated fasting C-peptide testing requirement:

- Insulinopenia (defined as fasting C-peptide level less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method).

For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) less than 50ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory’s measurement method.2

- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/dL.
- Levels only need to be documented once in the medical records.

1 BCBSNC MEDICAL POLICY 7/2011
2
• Fasting C-peptide levels are not required for patients diagnosed at younger than 12 years of age

**AND**

2) Patients must meet one of the following criteria (A, B, or C):

A. Patient requires multiple insulin doses, usually more than three per day and usually with mixed long-acting/short acting insulin. These multiple and mixed doses have been required for a period of:
   1. at least 6 months and all of the following criteria are met:
      a. Erratic blood sugar, ketoacidosis, or symptomatic hypoglycemia in spite of maximal patient compliance and intermittent dosing; and
      b. Hgb A-1C is greater than 7.0% unless there is documented frequent hypoglycemia that contributes to a low or normal Hgb A-1C; and
      c. The patient is involved in a comprehensive diabetes care program (e.g., the THC or other diabetes disease management program) and
      d. An endocrinologist or physician with similar skill and training in the management of external insulin pumps prescribes the pump or involved with the care of the patient. (This may include initial consult visit and phone or written follow-up)

2. Less than 6 months but more than 3 months and the patient has documented extenuating circumstances. These cases may be reviewed on an individual consideration basis.

B. Patient with gestational diabetes or when pregnancy occurs or is anticipated within 3 months in a previously diagnosed diabetic with ANY of the following indications:
   1. Erratic blood sugars in spite of maximal patient compliance and split dosing; or
   2. Other evidence that adequate control is not being achieved.

C. A member with chronic renal failure and brittle diabetes could benefit from tight control with an insulin pump as long as he/she is not having renal dialysis.³

Note: The recommended goal is for a patient’s Hgb A-1C to be less than 7.

External insulin pumps are not recommended when the medical guidelines shown above are not met.

CPT codes: *A4230, A4231, A4232, A9274, E0784, S9145*

Replacement of insulin pump must not solely be for updated model or convenience

³ BCBSNC Medical Policy July 2011
4 Aetna Clinical Policy 0161
DEFINITIONS:

1. **Strongly Motivated**
   - At least 6 monthly visits with a certified diabetic educator
   - Completes a self blood glucose monitoring log for at least a 6 month period
   - At least 6 monthly visits with nutritionists, if weight is greater than 5% of ideal body weight
   - Participation in an exercise program/regimen

2. **Sub-Optimal Control of Diabetes (Objective Findings)**
   - Multiple hospitalizations or ER visits for hypo/hyperglycemia in the past 12 months
   - At least 3 bi-monthly Hemoglobin A1C > 2 % points from reference range after appropriate conventional medical management has been consistently implemented by the patient and the physician.
   **Replacement of insulin pump must not solely be for updated model or convenience**

**COMPLIANCE REQUIREMENTS**

- 3 to 4 insulin injections per day
- All appropriate pharmaceutical agents have been utilized
- Weight is within 5% of ideal body weight
- Documented evidence of 6 months participation in an exercise program/regimen
- Participation in the Total Health Care’s Diabetic Disease Management Program